

## **REMARKS**

### **1. Summary of the Office Action**

Claim 1 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over applicant's admitted prior art, in view of U.S. patent no. 5,394,322, hereinafter referred to as ("Hansen, Peter"). Newly added claims 38-66 are pending in this application.

### **2. Specification**

Applicant has amended the specification to update the "Cross-Reference to Related Applications" section and it is submitted that the Examiner's concerns in that regard have been addressed.

### **3. Double Patenting**

The Examiner has rejected claim 1 under the judicially created doctrine of obviousness-type double patenting in view of United States patent no. 6,233,539. Claim 1 has been cancelled without prejudice rendering this rejection moot.

### **4. Response to § 103 Rejections**

The examiner has rejected claim 1 under 35 U.S.C. 103(a) as being obvious in view of applicant's admitted prior art and US patent no. 5,394,322. Claim 1 has been cancelled rendering its rejection moot. However, applicant respectfully traverses the rejection for the reasons set forth below particularly relating to the newly added claims.

Newly added claim 37 recites an electronic data receiver configured for receiving self-care values  $S_{M(t_i)}$  of a patient; a memory for storing optimal control parameter values  $R(t_i)$  and  $R(t_j)$ , a prior disease control parameter value  $X(t_i)$ , optimal self-care values  $O_{M(t_i)}$ , and one or more scaling factors  $K_M$ ; a microprocessor, in communication with said input device and said memory, for calculating a further value for enabling corrective action to be performed to prevent hypoglycemia or hyperglycemia, said further value being based on said self-care values  $S_{M(t_i)}$  and  $O_{M(t_i)}$ , said control parameter values  $X(t_i)$ ,  $R(t_i)$  and  $R(t_j)$ , and said scaling factors  $K_M$ ; and an output port for outputting a signal configured according to said further value, thereby enabling said corrective action to be performed to prevent said hypoglycemia or hyperglycemia.

As understood, neither applicant's admitted prior art nor US patent no. 5,394,322 teach or suggest, alone or in combination, all of these features recited at claim 37. In particular, neither applicant's admitted prior art nor US patent no. 5,394,322 teach or suggest calculating a value for enabling corrective action to be performed to prevent hypoglycemia or hyperglycemia that is based on self-care values  $S_{M(t_i)}$  and  $O_{M(t_i)}$ , control parameter values  $X(t_i)$ ,  $R(t_i)$  and  $R(t_j)$ , and scaling factors  $K_M$ , and outputting a signal configured according to this value, thereby enabling the corrective action to be performed to prevent the hypoglycemia or hyperglycemia

Newly added claim 40 recites an electronic data receiver for receiving a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$  and for entering an insulin dose value  $I_k$  representative of an insulin dose administered to the patient prior to time  $t_d$ ; a memory for storing an insulin sensitivity value representative of an insulin sensitivity of the patient and for storing information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action

remaining at time  $t_d$  from said insulin dose; a processor connected to said electronic data receiver and said memory for determining said insulin action value  $F_k(t_d)$  and for determining a further value for enabling a corrective action to prevent hypoglycemia or hyperglycemia, wherein said processor determines said further value in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value  $I_k$ , said insulin sensitivity value, and said insulin action value  $F_k(t_d)$ ; an interpolation formula to calculate the insulin action value  $F_k(t_d)$  programmed into the processor; a formula to calculate the further value programmed into the processor; and an output port coupled with said processor for outputting a signal configured according to said further value, thereby enabling corrective action to be performed to prevent hypoglycemia or hyperglycemia based on said signal.

As understood, neither applicant's admitted prior art nor US patent no. 5,394,322 teach or suggest, alone or in combination, all of these features recited at claim 40. In particular, neither applicant's admitted prior art nor US patent no. 5,394,322 teach or suggest determining a value for enabling a corrective action to prevent hypoglycemia or hyperglycemia, wherein a processor determines the value in dependence upon blood glucose value  $G(t_d)$ , insulin dose value  $I_k$ , an insulin sensitivity value, and insulin action value  $F_k(t_d)$ , and outputting a signal configured according to this value, thereby enabling corrective action to be performed to prevent hypoglycemia or hyperglycemia based on the signal.

Newly added claim 55 recites an electronic data receiver for entering a blood glucose value  $G(t_d)$  representative of a blood glucose concentration of the patient at time  $t_d$  and for entering an insulin dose value representative of an insulin dose administered to the patient prior to time  $t_d$ ; a memory for storing maximum and minimum values defining a target blood glucose range of the patient, an insulin sensitivity value representative of

an insulin sensitivity of the patient, and information for determining an insulin action value  $F_k(t_d)$  representative of a fraction of insulin action remaining at time  $t_d$  from said insulin dose; a processor connected to said electronic data receiver and said memory for determining said insulin action value  $F_k(t_d)$ , for determining a further value enabling a corrective action to be performed to prevent hypoglycemia or hyperglycemia at a later time  $t_j$ , and for determining a corrective action for the patient when said further value indicates that a future blood glucose value of the patient will fall outside said target range without said corrective action, wherein said processor determines said further value in dependence upon said blood glucose value  $G(t_d)$ , said insulin dose value, said insulin sensitivity value, and said insulin action value  $F_k(t_d)$ ; and a display connected to said processor for recommending said corrective action to the patient.

As understood, neither applicant's admitted prior art nor US patent no. 5,394,322 teach or suggest, alone or in combination, all of these features recited at claim 55. In particular, neither applicant's admitted prior art nor US patent no. 5,394,322 teach or suggest determining a value enabling a corrective action to be performed to prevent hypoglycemia or hyperglycemia at a later time  $t_j$ , and determining a corrective action for the patient when the value indicates that a future blood glucose value of the patient will fall outside the target range without the corrective action, wherein the value is determined based on blood glucose value  $G(t_d)$ , insulin dose value, insulin sensitivity value, and insulin action value  $F_k(t_d)$ , and wherein a display is connected to a processor for recommending the corrective action to the patient.

In view of the above, it is respectfully submitted that the application is now in condition for allowance. The Examiner's further examination and consideration are respectfully requested.

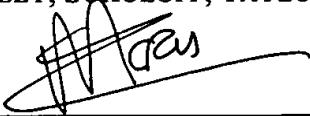
If there are any additional charges, please charge Deposit Account No. 02-2666.

If a telephone interview would in any way expedite the prosecution of the present application, the Examiner is invited to contact André Marais at (408) 947-8200 ext. 204.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: 04/28/ 2004

  
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